

REMARKS

Applicants have carefully reviewed the Office Action mailed February 10, 2005, prior to preparing this response. Currently claims 1-26 are pending in the application, wherein claims 1-26 have been rejected. Claim 27 has been added with this Amendment. Support for claim 27 may be found, for example, at page 6, lines 17-22. Applicants assert no new matter has been added. Favorable consideration of the following remarks regarding the status of the application is requested.

Claim 16 is objected to as containing the registered trademark "Dacron", owned by DuPont. Applicants respectfully traverse this objection. Contrary to the Examiner's assertion that the M.P.E.P. prohibits the claiming of registered trademarks, Applicants assert the guidelines of the M.P.E.P. in fact state "examiners are authorized to permit the use of the trademark if it is distinguished from common descriptive nouns by capitalization." M.P.E.P. §608.01(v)(I) (emphasis added). At no point does the M.P.E.P. prohibit the inclusion of registered trademarks in claimable subject matter. The guidelines provided regarding claim terminology state that "[t]he meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its import." M.P.E.P. §608.01(o). Therefore, the use of a trademark is allowable if the trademark has a fixed and definite meaning and the product to which the product refers is set out in clear language in the specification. See M.P.E.P. §608.01(v)(I). Applicants assert that Dacron has gained a fixed and definite meaning in the industry as a polymer material having suitable medical characteristics. Furthermore, Dacron has been clearly described in the specification as a synthetic polyester material used for its strength and biocompatibility available from E. I. du Pont de Nemours and Company located in Wilmington, Delaware. See page 10, lines 5-8. Therefore, Applicants assert the specification provides a clear and definite meaning for the term "Dacron" as used in claim 16. The M.P.E.P. does not provide for *per se* prohibition of claims containing a registered trademark, thus, withdrawal of the objection is requested.

Claims 1-10 and 17-22 stand rejected under 35 U.S.C. §102(e) as being anticipated by Levinson et al. (U.S. Patent No. 6,277,139). Applicants respectfully traverse this rejection.

Claims 1 and 10 recite an actuatable stop disposed at the distal end of the core wire, wherein the actuatable stop is movable between a collapsed position and an expanded position. The Examiner asserts element 20 of Levinson defines an actuatable stop as currently claimed. The Examiner's reliance on element 20, a filter frame of a filter, as teaching an actuatable stop is clearly untenable.

During patent examination, patent claims must be given their broadest reasonable interpretation consistent with the specification. See M.P.E.P. §2111 (emphasis added). "The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach." M.P.E.P. §2111, citing *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999). Applicants assert the interpretation given the term "actuatable stop" by the Examiner is neither consistent with the specification nor consistent with that of one skilled in the art.

An actuatable stop as currently claimed and described in the instant specification is an element disposed at the distal end of a guidewire to prevent advancement of another medical device, such as an embolic filter, distally beyond the stop. The stop is actuatable between a collapsed position and an expanded position. Thus, the guidewire may be readily navigated through a vasculature while the actuatable stop is in the collapsed position. After placement in the vasculature, the actuatable stop may be expanded. While in the expanded position, the actuatable stop may effectively prevent distal travel of another medical device, such as an embolic filter, beyond the actuatable stop. See, for example, Specification, page 6, lines 17-22. Thus, the actuatable stop is a distinct element dissimilar from an expandable filter. Therefore, the Examiner's interpretation of the actuatable stop as currently claimed is inconsistent with that provided in the specification.

Additionally, one skilled in the art will recognize a stop as an element of an elongate wire for preventing distal travel of another medical device, such as an embolic filter, extending over the elongate wire. For example, Levinson teaches a stop 16 for preventing longitudinal movement of a filter device 10 beyond stop 16. See Levinson,

column 6, lines 21-25. However, as stated previously Levinson fails to teach an actuatable stop moveable between a collapsed position and an expanded position.

The Examiner cites the filter frame 20 of a filter device 10, which may be expandable between a pre-deployed state and a deployed state, as teaching the actuatable stop as currently claimed. This is clearly an erroneous interpretation of the teachings of Levinson inconsistent with that reached by one skilled in the art. Levinson does disclose a stop 16 and identifies it as such. However, as stated above and in a previous response, the stop 16 disclosed in Levinson is not an actuatable stop moveable between a collapsed position and an expanded position. Apparently in reaching this same conclusion, the Examiner unreasonably asserts reliance on the filter frame 20 of the filter device 10 as teaching the claimed actuatable stop. This position is untenable. First, Levinson discloses “[o]ne important functional feature of the present invention involves the free movement of guide wire 12 within and through filter device 10.” Levinson, column 6, lines 57-60. The fact that the filter device 10 is free to move along guide wire 12 negates any assertion that the filter frame 20 may be characterized as a stop as suggested by the Examiner. It is the stop 16 that prevents longitudinal movement of the filter device 10 beyond stop 16. A filter device 10 slidable along guide wire 12 necessarily does not act as a stop. Additionally, Levinson does indeed teach a stop 16, therefore, asserting the filter frame 20 of the filter device 10 is also a stop as currently claimed would be contrary to the teachings of Levinson.

The Examiner’s interpretation of the teachings of Levinson, as well as the interpretation of the invention currently claimed, is clearly erroneous in view of the current specification and the conclusion one skilled in the art would reach. The present specification provides sufficient disclosure to support a reasonable interpretation of the currently claimed invention. Furthermore, one of skill in the art would not conclude that the filter frame 20 of the filter device 10 of Levinson is an actuatable stop.

Additionally, even if the Examiner erroneously maintains the filter frame 20 is an actuatable stop, Levinson still fails to teach the claimed invention. Namely, the claimed invention also includes a filter disposed on the core wire. If the Examiner maintains the filter frame 20 of the filter device 10 is an actuatable stop, then Levinson fails to teach the limitation of “a filter disposed on the core wire” since Levinson teaches only one filter

device 10, which the Examiner asserts is an actuatable stop. Therefore, an element-by-element analysis would reveal Levinson fails to teach each element of the claimed invention necessary in order to anticipate the claims. In order to anticipate, "the identical invention must be shown in as complete detail as is contained in the claim." M.P.E.P. §2131, quoting *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

For the reasons stated above, claims 1 and 10 are clearly patentable over Levinson. Claims 2-9 and 17-22 depend from either claim 1 or claim 10 and include additional significant limitations; therefore, these claims are also believed to be in condition for allowance.

Claims 13, 15 and 16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Levinson et al. (U.S. Patent No. 6,277,139) in view of Dubrul et al. (U.S. Patent No. 6,602,265). Applicants respectfully traverse this rejection.

Applicants assert a *prima facie* case of obviousness has not been established at least because each and every element of the claimed invention is not taught or suggested by the combination of references. The deficiencies of Levinson have been discussed above in detail. It is apparent from the above remarks that Levinson at least fails to teach an articulating guidewire having an actuatable stop moveable between a collapsed position and an expanded position as currently claimed in claim 10. Likewise, Dubrul also fails to teach at least this element of the claimed invention. Furthermore, their independent shortcomings are not remedied by their combination. Therefore, due to the deficiencies of the references, no *prima facie* case has been established by the cited combination of references. Applicants assert claims 13, 15 and 16 are currently in condition for allowance.

Claims 11, 12 and 14 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Levinson et al. (U.S. Patent No. 6,277,139) in view of Tate (U.S. Patent No. 3,841,308). Applicants respectfully traverse this rejection.

Applicants assert a *prima facie* case of obviousness has not been established at least because each and every element of the claimed invention is not taught or suggested by the combination of references. The deficiencies of Levinson have been discussed above in detail. It is apparent from the above remarks that Levinson at least fails to teach

an articulating guidewire having an actuatable stop moveable between a collapsed position and an expanded position as currently claimed in claim 10. Likewise, Tate also fails to teach at least this element of the claimed invention. Furthermore, their independent shortcomings are not remedied by their combination. Therefore, due to the deficiencies of the references, no *prima facie* case has been established by the cited combination of references. Applicants assert claims 11, 12 and 14 are currently in condition for allowance.

Claims 23-26 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Cohen et al. (U.S. Patent No. 5,167,239) in view of Dubrul et al. (U.S. Patent No. 6,602,256). Applicants respectfully traverse this rejection.

In order to establish a *prima facie* case of obviousness: there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings; there must be a reasonable expectation of success; and the prior art combination must teach or suggest all of the claim limitations. See M.P.E.P. §2143. The references cited by the Examiner fail to meet the criteria to establish a *prima facie* case.

“The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.” M.P.E.P. §2143.01, citing *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990) (emphasis in original). There is no motivation to combine the teachings of Cohen with those of Dubrul, and neither reference provides the desirability for the combination. “The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant’s disclosure.” M.P.E.P. §2143, citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Furthermore, the cited prior art combination fails to teach or suggest all the claim limitations of the rejected claims. Rejected claim 23 states,

A method for placing an articulating guidewire in the vasculature, comprising the steps of:

providing an articulating guidewire comprising an elongated core wire having a longitudinal axis, a proximal end and a distal end; and an actuatable stop disposed at the distal end of the core wire, said actuatable stop moveable between a collapsed position and an expanded position;

inserting the guidewire into the lumen of a blood vessel;
positioning a distal portion of the guidewire beyond a lesion or other protrusion within the body;
actuating the actuatable stop from the collapsed position to the expanded position; and
advancing a filter on the guidewire to the stop.

Neither Cohen nor Dubrul teach, individually or collectively, a method of placing an articulating guidewire in the vasculature as currently claimed. Cohen appears to teach an anchorable guidewire including an inflatable anchoring balloon to facilitate anchoring and holding the guidewire in a particular body passageway. See Cohen, column 3, lines 64-68. Cohen suggests the anchoring balloon facilitates holding the guidewire in place while manipulating or exchanging a catheter, scope or other instrument which has been inserted over the guidewire. See Cohen, column 3, lines 3-23. At no point does Cohen teach placement of an articulating guidewire having an actuatable stop including the step of actuating the actuatable stop from a collapsed position to an expanded position or the step of advancing a filter on the guidewire to the stop. The Examiner's apparent assertion that the anchoring balloon is an actuatable stop as currently claimed and that Cohen teaches the method taught in claim 23 is unsupported by the teachings of Cohen. As stated above, the anchoring balloon taught by Cohen is inflated to anchor the guidewire in a body passageway. There is no teaching, suggestion, or other motivation in Cohen for one skilled in the art to conclude the anchoring balloon is a stop for limiting the distal travel of a filter as currently claimed. Applicants assert the Examiner must step backward in time to avoid impermissible hindsight. See M.P.E.P. §2142. Knowledge of the Applicant's own disclosure must be put aside in evaluating the teachings of the prior art. The inquiry for the Examiner is whether the claimed invention "as a whole" would have been obvious at the time of the Applicant's invention. See M.P.E.P. §2142. As stated above, a stop as currently claimed has a particular import to one of ordinary skill in the art. There is no suggestion in Cohen, and one of ordinary skill in the art would not suggest the proposition of the anchoring balloon as an actuatable stop. Therefore, the teachings of Cohen would not put one of ordinary skill in the art in possession of the claimed invention.

Likewise, Dubrul also fails to teach at least this limitation of the rejected claims. Dubrul seems to teach a method of removing tissue from the body, and the use of a guidewire is incidental to the teachings of Dubrul. The Examiner apparently relies on Dubrul as teaching the step of advancing a filter on the guidewire to the stop. However, even if the trapping device (TRAP) taught by Dubrul is construed as teaching a filter, at no point does Dubrul teach or suggest a stop or advancing a filter on a guidewire to a stop. Because the combination of Cohen and Dubrul fail to teach every limitation of the claimed invention, no *prima facie* case of obviousness has been established.

Additionally, regarding claims 25 and 26, neither Cohen nor Dubrul teaches an actuator moveable about a core wire as claimed in claim 25. Because the combination of Cohen and Dubrul fail to teach every limitation of the claimed invention, no *prima facie* case of obviousness has been established regarding claims 25 and 26.

Applicants assert the Examiner has not established a *prima facie* case of obviousness regarding the cited combination for at least the reasons stated above. Therefore, claims 23-26 are believed to be in condition for allowance. Newly added claim 27 is similarly believed patentable over the prior art.

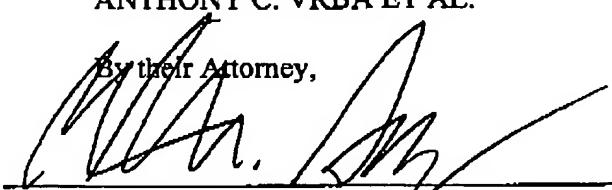
Reexamination and reconsideration are respectfully requested. It is submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney.

Respectfully submitted,

ANTHONY C. VRBA ET AL.

By their Attorney,

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